

## REMARKS

### I. PRELIMINARY REMARKS

Claims 46, 47, 65, 68-71 and 80 have been amended. Claims 46, 82, 88 and 91 have been canceled. Claims 98-101 have been added. Claims 45, 47, 48, 50-54, 65, 66, 68-71, 73-81, 83-87, 89, 90 and 92-101 remain in the application. Reexamination and reconsideration of the application, as amended, are respectfully requested.

On page 11, the Office Action indicates that claims 52-54 and 86 have been rejected based on the Umeda patent. Although claim 86 depends from independent claim 52, claims 53 and 54 do not. Claim 53 and 54 depend from independent claim 47, and independent claim 47 was not rejected based on the Umeda patent. Accordingly, applicant has assumed that the reference to claims 53 and 54 on page 11 was a typographical error. ***Clarification is hereby requested.***

The issues associated with claims 53 and 54 notwithstanding, applicant notes with appreciation that the Examiner went to great lengths to explain the basis for each rejection.

### II. REJECTIONS UNDER 35 U.S.C. §§ 102 AND 103

#### A. The Rejections

Claims 47, 48, 50, 51, 66, 68-71, 73, 74 and 92-96 have been rejected under 35 U.S.C. § 102 as being anticipated by U.S. Patent No. 5,336,182 to Lundquist ("the Lundquist '182 patent"). Claims 80-82 and 89-91 have been rejected under 35 U.S.C. § 103 as being unpatentable over the combined teachings of the Lundquist '182 patent and U.S. Patent No. 6,450,948 to Matsuura ("the Matsuura '948 patent").

Claims 65, 87 and 88 have been rejected under 35 U.S.C. § 102 as being anticipated by the Matsuura '948 patent.

Claims 45, 46, 52, 79, 86 have been rejected under 35 U.S.C. § 102 as being anticipated by U.S. Patent No. 5,255,668 to Umeda (“the Umeda ‘688 patent”).

Claims 75-78 and 83-85 have been rejected under 35 U.S.C. § 103 as being unpatentable over the combined teachings of the Umeda ‘688 patent and the Matsuura ‘948 patent.

The rejections under 35 U.S.C. §§ 102 and 103, which have not been rendered moot by the claim cancellations/amendments discussed below, are respectfully traversed to the extent that they are applicable to the claims as amended above. Reconsideration thereof is respectfully requested.

## **B. The Cited References**

The Lundquist ‘182 patent is directed to a steering mechanism that may be inserted into the lumen of a non-steerable device and used to steer the non-steerable device to the target location. [Column 3, lines 57-66.] In some implementations, the steering mechanism may be removed from the non-steerable device after the non-steerable device reaches the target location, while in others, the steerable device may be secured to the non-steerable device with adhesive (Figure 25). Referring to Figures 1-5, the steering mechanism 10 includes flexible shaft 30 with an internal coil spring 170, a steering wire 120 with a distal end 150 that is secured to a lead spring 230 by a weld 260, and a ferrule 190 mounted on the coil spring 170 with slots 210 and 220 that receive the lead spring 230. The ferrule 190 may also be eliminated and the lead spring 230 mounted in the end of the coil spring 170. [Figure 36; and column 5, lines 34-40.]

The Matsuura ‘948 patent discloses a variety of deflectable tips for use with steerable surgical instruments. The instrument illustrated in Figures 1-5 includes a deflectable tip section 40. The deflectable tip section 40, which is referred to in the Office Action, includes proximal and distal collars 50A and 50B on opposite ends of a flexible tubular body 52. A pair of strengthening members 54 are positioned within the wall of the tubular body 52 and extend from the end collar 50A to the end collar 50B. The deflectable tip is illustrated in Figures 11 and 12 was also referred to in the Office Action. Here too, the

deflectable tip includes collars 350A and 350B, a tubular body 352, and strengthening members 354A and 354B.

The Umeda '668 patent discloses a bending device that may be used in an endoscope or catheter. Referring to Figures 1 and 2, the illustrated endoscope includes a hollow body 1, with an insertion portion 2 and a bending portion 3, and a pair of wires 8a/8b that are used to deflect the bending portion. [Column 3, lines 28-32 and 56-65.] The bending portion 3 has a bending device 9. The bending device 9 includes a thin plate 10, a coil 20, a tip member 30, a connecting tube 40 that connects the coil to the tip member, and a connecting tube 50 that connects the coil to the insertion portion 2. The connecting tubes 40 and 50 include slits 42a/42b and 51a/51b for the thin plate 10. The connecting tube 40 also includes an extra set of slits 41a/41b that allow the distal ends of the wires 8a/8b to be secured to the connecting tube 40. [Column 6, line 62 to column 7, line 7.] The connecting tube 50 does not include an extra set of slits.

### C. Discussion Concerning Claims 45 and 75-79

Independent claim 45 calls for the combination of elements previously recited in now-canceled claim 46. The combination includes, *inter alia*, “an elongate body defining a proximal portion and a distal portion,” “a steering wire having a distal portion,” “an anchoring member” and “means, directly connected to the anchoring member, for preventing compression ...” and “a tubular member, that is a partial circle in cross-section and has a **slot in which a portion of the steering wire is located**, positioned ...” The respective combinations defined by claims 75-79 include, *inter alia*, the elements recited in claim 45.

The Umeda '668 patent fails to teach or suggest the claimed combinations. For example, the Office Action appears to have asserted that (1) one of the Umeda wires 8a/8b corresponds to the claimed “steering wire,” (2) a portion of the Umeda connecting tube 50 corresponds to the claimed “tubular member,” and (3) one of the slits 51a/51b corresponds to the claimed “slot.” [Office Action at pages 10-11.] Even assuming for the sake of argument that this is a reasonable interpretation of independent claim 45, the Umeda wires

8a/8b are not located within the slits 51a/51b. The thin plate 10 is located within the slits 51a/51b, and the wires 8a/8b are circumferentially offset from the slits 51a/51b by 90 degrees. The Office Action also asserted, in the context of now-canceled claim 46, that:

Umeda discloses that a portion of the steering wire is positioned within the slot (Fig. 2 discloses that the steering wires 8a/8b are positioned within the slots 51a/51b similar to the arrangement depicted in Fig. 5).

[Office Action at page 11.] This assertion is incorrect. The connecting tube 50 **does not include an additional set of slits**, such as those that are provided on the connecting tube 40 to facilitate the connection of the wires 8a/8b to the connecting tube 40. Instead, as illustrated in Figure 2 and described in column 6, lines 62-68, “wires 8a and 8b extend **axially near the inner peripheral surfaces** of the connecting tube 50 [and] the coil 20.” [Emphasis added.]

As the Umeda '668 patent fails to teach or suggest each and every element of the combination recited in independent claim 45, applicant respectfully submits that the rejection of claims 45 and 79 under 35 U.S.C. § 102 should be withdrawn.

With respect to claims 75-78, applicant respectfully submits the teachings Matsuura '948 patent would not have suggested moving the Umeda wires 8a/ 8b into the slits 51a/51b that hold the thin plate 10, or adding an extra pair of slits to the connecting tube 50. As such, claims 75-78 are patentable for at least the same reasons as independent claim 45 and the rejection of claims 75-78 under 35 U.S.C. § 103 should also be withdrawn.

#### **D. Discussion Concerning Claims 47, 48, 50, 51, 66, 80 and 81**

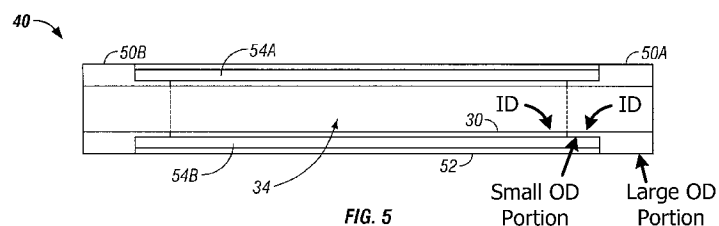
At the outset, applicant notes that independent claim 47 now calls for the combination previously recited in now-canceled dependent claim 82. Accordingly, the rejection of claims 47, 48, 50, 51 and 66 under 35 U.S.C. § 102 has been rendered moot. In order to advance prosecution, applicant has treated the rejection under 35 U.S.C. § 103 as being applicable to 47, 48, 50, 51 and 66, in addition to claims 80 and 81.

Independent claim 47 calls for a combination of elements including, *inter alia*, “an elongate body defining ... a distal portion and including a wall defining an inner surface, an outer surface and a lumen” and “a stiffening member associated with the distal portion of the elongate body and **located within the elongate body wall between the inner surface and the outer surface.**” The respective combinations defined by claims 48, 50, 51, 66, 80 and 81 include, *inter alia*, the elements recited in claim 47.

The Office Action has failed to establish a *prima facie* case of obviousness of the claimed combinations. For example, the Office Action has asserted that (1) the Lundquist ferrule 190 corresponds to the claimed “anti-tear device,” (2) the Matsuura proximal collars 50A/350A are located within a wall of the associated tubular body 52/352, and (3) based on the teachings of Matsuura ‘948 patent, it would have been obvious to move the Lundquist ferrule 190 into the wall of the flexible shaft 30. [Office Action at page 2 and 15.] There are a variety of errors associated with these assertions.

With respect to the first assertion, the Lundquist ferrule 190 is not an “anti-tear device.” It is an optional device that used mount the lead spring 230 on the end of coil spring 170.

Turning to the second assertion, the Matsuura collars 50A/350A are not located within a wall of the associated tubular body 52/352 between the inner and outer surfaces. Referring to Figure 5, which is reproduced here with indica added to aid the discussion, the collar 50A includes a large outer diameter (“OD”) portion and a small OD portion. The large OD portion of the collar 50A is certainly not located within the wall of the tubular body 52 between the inner and outer surfaces thereof. With respect to the small OD portion of the collar 50A, the inner diameter (“ID”) of the small OD portion is **the same as** ID of the tubular body 52. The ID of the tubular body 52 is defined by the inner surface of the tubular body wall. As such, the small OD portion of the collar 50A cannot be within the wall between the inner and outer surface. Referring to Figure



11, the collar 350A does not appear to even have a small OD portion and, instead, appears to simply be an annular structure that abuts the end of the associated tubular body 352.

As for the third assertion, applicant respectfully submits that Matsuura collars 50A/350A are not even remotely related to a ferrule (such as the Lundquist ferrule 190) that is used to mount a lead spring on the end of coil spring within the central lumen of a catheter shaft. The Matsuura collars 50A/350A would not, therefore, have suggested modifications related to the Lundquist ferrule 190 or the location thereof. That issue notwithstanding, given that no portion of the Matsuura collars 50A/350A are located within an elongate body wall between the inner and outer surfaces thereof, the Matsuura '948 patent would not have suggested moving the Lundquist ferrule 190 to a location within the wall of the Lundquist flexible shaft 30 and between the inner and outer surfaces thereof.

As illustrated above, the Lundquist '182 and Matsuura '948 patents fail to establish a *prima facie* case of obviousness with respect to the invention defined by independent claim 47. The rejection of claims 47, 48, 50, 51, 66, 80 and 81 under 35 U.S.C. § 103 should, therefore, be withdrawn.

#### **E. Discussion Concerning Claims 52 and 83-86**

Independent claim 52 calls for a combination of elements including, *inter alia*, “an elongate body,” “a steering wire,” “a stiffening member associated with the distal portion of the elongate body” and “a substantially c-shaped anti-tear device with a slot associated with the stiffening member.” Claim 52 also indicates that “**a portion of the steering wire is positioned within the slot.**” The respective combinations defined by claims 83-86 include, *inter alia*, the elements recited in claim 52.

The Umeda '668 patent fails to teach or suggest the claimed combinations. For example, the Office Action appears to have asserted that (1) one of the Umeda wires 8a/8b corresponds to the claimed “steering wire,” (2) a portion of the Umeda connecting tube 50 corresponds to the claimed “tubular member,” (3) there is an extra set of slits (in addition to

the slits 51a/51b for the thin plate 10) in the connecting tube 50, and (4) one of the “extra” slits corresponds to the claimed “slot.” [Office Action at pages 11-12.] As discussed in Section II-C above, the Umeda connecting tube 50 **does not include an additional set of slits**, such as those that are provided on the connecting tube 40 in order to facilitate the connection of the wires 8a/8b to the connecting tube 40. Instead, as illustrated in Figure 2 and described in column 6, lines 62-68, “wires 8a and 8b extend **axially near the inner peripheral surfaces** of the connecting tube 50 [and] the coil 20.” [Emphasis added.]

As the Umeda ‘668 patent fails to teach or suggest each and every element of the combination recited in independent claim 52, applicant respectfully submits that the rejection of claims 52 and 86 under 35 U.S.C. § 102 should be withdrawn.

With respect to claims 83-85, applicant respectfully submits the teachings Matsuura ‘948 patent would not have suggested moving the Umeda wires 8a/8b into the slits 51a/51b that hold the thin plate 10, or adding an extra pair of slits to the connecting tube 50. As such, claims 83-85 are patentable for at least the same reasons as independent claim 52 and the rejection of claims 83-85 under 35 U.S.C. § 103 should also be withdrawn.

#### F. Discussion Concerning Claims 65 and 87

Independent claim 65 calls for the combination of elements previously recited in now-canceled claim 88. The combination includes, *inter alia*, “an elongate body defining a proximal portion and a distal portion and including a wall defining an inner surface, an outer surface and a lumen,” “a steering wire,” “a stiffening member” and “an anti-tear device ... **located within the distal portion of the elongate body wall between the inner surface and the outer surface.**” The combination defined by claim 87 includes, *inter alia*, the elements recited in claim 65.

The Matsuura ‘948 patent fails to teach or suggest the claimed combinations. For example, in the context of now-canceled claim 88, the Office Action asserted that the Matsuura proximal collars 50A/350A are located within a wall of the associated tubular body 52/352 between the inner and outer surface thereof. Applicant respectfully submits

that this assertion is incorrect. Referring to Figure 5 of the Matsuura '948 patent, which is reproduced in Section II-D above, the collar 50A includes a large OD portion and a small OD portion. The large OD portion is not located within the wall of the tubular body 52 between the inner and outer surfaces thereof. The ID of the small OD portion of the collar 50A is **the same as** ID of the tubular body 52, which is defined by the inner surface of the tubular body wall. As such, the small OD portion of the collar 50A cannot be within the wall between the inner and outer surface. Referring to Figure 11, the collar 350A does not appear to have a small OD portion and, instead, appears to simply be an annular structure that abuts the end of the associated tubular body 352.

As the Matsuura '948 patent fails to teach or suggest each and every element of the combination recited in independent claim 65, applicant respectfully submits that the rejection of claims 65 and 87 under 35 U.S.C. § 102 should be withdrawn.

#### **G. Discussion Concerning Claim 68, 89 and 90**

At the outset, applicant notes that independent claim 68 now calls for the combination previously recited in now-canceled dependent claim 91. Accordingly, the rejection of claim 68 under 35 U.S.C. § 102 has been rendered moot. In order to advance prosecution, applicant has treated the rejection under 35 U.S.C. § 103 as being applicable to 68 in addition to claims 89 and 90.

Independent claim 68 calls for a combination of elements including, *inter alia*, “an elongate body ... including a wall defining an inner surface, an outer surface and a lumen,” “a stiffening member associated with the distal portion of the elongate body” and “**anti-tear means**, associated with the stiffening member and located **within the elongate body wall between the inner surface and the outer surface**, for increasing the elongate body surface area over which the force is applied when the stiffening member is bent to prevent the stiffening member from tearing through the elongate body.” The respective combinations defined by claims 89 and 90 include, *inter alia*, the elements recited in claim 68.

The Office Action has failed to establish a *prima facie* case of obviousness of the claimed combinations. For example, the Office Action asserted that (1) the Lundquist ferrule 190 corresponds to the claimed “anti-tear means,” (2) the Matsuura proximal collars 50A/350A are located within a wall of the associated tubular body 52/352, and (3) based on the teachings of Matsuura ‘948 patent, it would have been obvious to move the Lundquist ferrule 190 into the wall of the flexible shaft 30. [Office Action at pages 3-5 and 15.] There are a variety of errors associated with these assertions.

With respect to the first assertion, the Lundquist ‘182 patent does not indicate that the ferrule 190 performs the function set forth in the means-plus-function element.

Turning to the second assertion, the Matsuura collars 50A/350A are not located within a wall of the associated tubular body 52/352 between the inner and outer surfaces. [See the discussion in Section II-D above.]

As for the third assertion, applicant respectfully submits that Matsuura collars 50A/350A are not even remotely related to a ferrule (such as the Lundquist ferrule 190) that is used to ***mount a lead spring on the end of coil spring within the central lumen*** of a catheter shaft. The Matsuura collars 50A/350A would not, therefore, have suggested modifications related to the Lundquist ferrule 190 or the location thereof. That issue notwithstanding, given that no portion of the Matsuura collars 50A/350A are located within an elongate body wall between the inner and outer surfaces thereof, the Matsuura ‘948 patent would not have suggested moving the Lundquist ferrule 190 to a location within the wall of the flexible shaft 30 and between the inner and outer surfaces thereof.

As illustrated above, the Lundquist ‘182 and Matsuura ‘948 patents fail to establish a *prima facie* case of obviousness with respect to the invention defined by independent claim 68. The rejection of claims 68, 89 and 90 under 35 U.S.C. § 103 should, therefore, be withdrawn.

#### H. Discussion Concerning Claims 69-71, 73, 74 and 92-96

Independent claims 69-71 call for respective combinations of elements including, *inter alia*, “an elongate body defining ... a distal portion and including a wall defining an inner surface, an outer surface and a lumen,” “a steering wire” and “an **anchoring member located within the distal portion of the elongate body wall between the inner surface and the outer surface** and secured to the steering wire.” The combinations defined by claims 73, 74 and 92 include, *inter alia*, the elements recited in claim 69, the combinations defined by claims 93 and 94 include, *inter alia*, the elements recited in claim 70, and the combinations defined by claims 95 and 96 include, *inter alia*, the elements recited in claim 71.

The Lundquist ‘182 patent fails to teach or suggest the claimed combinations. For example, the Office Action now appears to have taken the position that the Lundquist weld 260 corresponds to the claimed “anchoring member.” [Office Action at page 5 and 6.] The Lundquist weld 260 is not, however, located with the wall of the flexible shaft 30 between the inner and outer surfaces thereof.

As the Lundquist ‘182 patent fails to teach or suggest each and every element of the respective combinations recited in independent claims 69-71, applicant respectfully submits that the rejection of claims 69-71, 73, 74 and 92-96 under 35 U.S.C. § 102 should be withdrawn.

#### III. NEWLY PRESENTED CLAIMS 98-101

Newly presented claims 98-101 respectively depend from independent claims 68-71 and are patentable for at least the same reasons as claim 68-71.

#### IV. CLOSING REMARKS

In view of the foregoing, it is respectfully submitted that the claims in the application are in condition for allowance. Reexamination and reconsideration of the

application, as amended, are respectfully requested. Allowance of the claims at an early date is courteously solicited.

If for any reason the Examiner finds the application other than in condition for allowance, the Examiner is respectfully requested to call applicant's undersigned representative at (310) 563-1458 to discuss the steps necessary for placing the application in condition for allowance.

The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-0638. Should such fees be associated with an extension of time, applicant respectfully requests that this paper be considered a petition therefor.

Respectfully submitted,

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